

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effects of the counseling Based on self-Efficacy in menopausal symptoms management in peri menopausal women

#### Protocol summary

##### Study aim

The effects of the counseling Based on self-Efficacy in menopausal symptoms management in peri menopausal women referred to health centers in mahabad in 2017-218

##### Design

The present study is a quasi-experimental, pretest-posttest with control group. Sampling in this study was done by selecting the health centers of Mahabad city randomly and selecting samples from each center. A total of 80 women were admitted to menopausal women in two groups (n = 40) and n = 40 (n = 40). The intervention group in this study was women of menopausal age who had criteria for entering the study. Control group In this study, women with menopausal status have criteria for entering the study

##### Settings and conduct

Firstly, a list of all health centers in Mahabad city was prepared. Subsequently, urban health centers were divided into two levels, 1 and 2, according to the opinion of the health center experts on the basis of cultural and socioeconomic status. At this stage each center's name was written in separate sheets and placed in a bag and selected by random method (simple random) from each center. At each level, a center for the control group and one center for the intervention group were assigned randomly from each node. From each center, 10 menopausal women were selected according to entry criteria.

##### Participants/Inclusion and exclusion criteria

Inclination to participate in research Iranian nationality  
Age between 45-55 years Residence in Mahabad city  
The absence of known physical, psychological and neurological diseases according to the patient  
No history of ovarian and uterine surgery  
Failure to develop artificial menopause.  
Unwillingness to continue research  
Missing more than two sessions in counseling sessions  
The occurrence of any stressful incidents for a patient or first degree family  
Removal of the ovary and

the womb  
Diagnosis of mental illness and psychiatric disorders during the study.

##### Intervention groups

Intervention group: The intervention group in this study was women of menopausal age who had inclusion criteria. Intervention for intervention group included self-efficacy counseling components on management of menopausal symptoms, which was performed in 6 sessions of a group of 45-60 minutes with intervals of one week  
The instruments used in this study were demographic questionnaire and Menopausal Symptom Scale questionnaire which was completed before and after counseling by the samples.  
Control group: Control group In this study, women were menopausal women who had criteria for entering the study  
They received routine care and a demographic questionnaire  
Menopausal scale was a questionnaire completed before and after counseling by samples

##### Main outcome variables

Independent variables in this research are self-efficacy-based counseling. The dependent variables in this study are menopausal symptoms and women around menopause. The underlying variables are age, the level of education of the wife and wife, the status of the wife and wife, the economic status, the length of the marriage by age, the menstruation, the number of pregnancies, the weight.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180108038275N1**

Registration date: **2018-03-04, 1396/12/13**

Registration timing: **retrospective**

Last update: **2018-03-04, 1396/12/13**

Update count: **0**

##### Registration date

2018-03-04, 1396/12/13

## Registrant information

### Name

Bayaneh Rahimi

### Name of organization / entity

### Country

Iran (Islamic Republic of)

### Phone

+98 44 4233 2958

### Email address

bayanrahimi57@yahoo.com

## Recruitment status

**Recruitment complete**

## Funding source

## Expected recruitment start date

2017-04-21, 1396/02/01

## Expected recruitment end date

2017-06-20, 1396/03/30

## Actual recruitment start date

2017-05-05, 1396/02/15

## Actual recruitment end date

2017-07-06, 1396/04/15

## Trial completion date

empty

## Scientific title

The effects of the counseling Based on self-Efficacy in menopausal symptoms management in peri menopausal women

## Public title

The effects of the counseling Based on self-Efficacy in menopausal symptoms management

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Inclination to participate in research Iranian nationality Age between 45-55 years Residence in Mahabad city The absence of known physical, psychological and neurological diseases according to the patient No history of ovarian and uterine surgery Failure to develop artificial menopause

### Exclusion criteria:

Unwillingness to continue research Missing more than two sessions in counseling sessions The occurrence of any stressful incidents for a patient or first degree family Removal of the ovary and the womb Diagnosis of mental illness and psychiatric disorders during the study

## Age

From **45 years** old to **55 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

Actual sample size reached: **80**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

## Ethics committee

### Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

### Street address

No.26, Ebne Sina Ave

### City

Mahabad

### Province

West Azarbaijan

### Postal code

5914867551

## Approval date

2017-03-02, 1395/12/12

## Ethics committee reference number

IR.Umsu.rec.1395.391

## Health conditions studied

### 1

## Description of health condition studied

Management of menopause symptoms

## ICD-10 code

## ICD-10 code description

## Primary outcomes

### 1

## Description

Management of menopausal symptoms

## Timepoint

Before intervention and 1 month after intervention

## Method of measurement

Menopause Rating Scale(MRS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group in this study was female menopausal women who had inclusion criteria. The intervention for the intervention group included self-efficacy counseling components on management of menopausal symptoms that was held in 6 sessions of a group of 45-60 minutes at intervals of one week. Tools The demographic questionnaire and the Menopausal Symptom Scale questionnaire, completed before and after counseling, were used in this study

#### Category

Rehabilitation

### 2

#### Description

Control group: The control group in this study was female menopausal women who had criteria for entering the study and received routine care. The demographic questionnaire and the menopausal scale scale questionnaire were completed before and after the consultation.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health centers in Mahabad city

##### Full name of responsible person

Bayaneh Rahimi

##### Street address

No. 26, Ebne Sina Ave

##### City

Mahabad

##### Province

West Azarbaijan

##### Postal code

5914867551

##### Phone

+98 44 4233 2958

##### Email

bayanrahimi57@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Iraj Mohebi

##### Street address

No. 26, Ebne Sina Ave.

#### City

Mahabad

#### Province

West Azarbaijan

#### Postal code

5914867551

#### Phone

+98 44 4233 2958

#### Email

bayanrahimi57@yahoo.com

#### Grant name

#### Grant code / Reference number

7000000

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Oroumia University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Bayaneh Rahimi

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Oroumia University of Medical Sciences

**Full name of responsible person**

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**Latest degree**

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**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Some of the data, such as information on the main outcome, can be shared

**When the data will become available and for how long**

Get started 6 months after printing results

**To whom data/document is available**

Researchers working in academia and academia

**Under which criteria data/document could be used**

nobody

**From where data/document is obtainable**

Email address

**What processes are involved for a request to access data/document**

First, by email, and if not possible by contact number

**Comments**

Mail for correspondence

**Person responsible for updating data****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Bayaneh Rahimi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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